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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,336	07/25/2005	Daniel Cohen	G-194US04PCT	9315
23557 7590 04/23/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1649	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/23/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,336	<b>Applicant(s)</b> COHEN ET AL.	
	<b>Examiner</b> Olga N. Chernyshev	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 43-54 and 63-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-54 and 63-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/11/6</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II in the reply filed on March 27, 2007 is acknowledged.

Claims 43-54 and 63-82 are under examination in the instant office action.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 43-45 and 63-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 43 is vague and indefinite as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the substrate for PP2A phosphatase. The instant specification discloses PP2A phosphatase as an enzyme, and the instant claimed method proposes to contact the PP2A phosphatase with a test compound to test the activity of PP2A phosphatase. Unless there is another endogenic activity of PP2A phosphatase not related to its enzymatic activity, that is intended to be tested, contacting of the PP2A phosphatase and a candidate modulator compound would not lead to any specific effect. This is especially true with respect to the recited comparison step where activity of PP2A phosphatase is supposed to be tested in the absence of the compound. Clarification is required.

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5. Claim 45 recites the limitation "natural ligand" and "an antisense RNA" in claim 43.

There is insufficient antecedent basis for these limitations in the claim. Specifically, it is not clear "ligand" or "antisense" of what molecular structures are encompassed by the claim.

6. Claims 63-74 are identified as being dependent from "any of claims 43" to 45.

Clarification of proper dependency is required.

7. Claims 69-71 recite the limitation "KCNQ2" in claims 43-45. There is insufficient antecedent basis for this limitation in the claims.

8. Claims 69-71 and 75-80 are vague and indefinite in so far as they employ the term "KCNQ2" as a limitation. This term appears to be novel, and without a reference to a precise amino acid sequence identified by a proper SEQ ID NO: one cannot determine the metes and bounds of "KCNQ2". Moreover, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "KCNQ2", an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

9. Claims 81-82 are indefinite for being dependent from indefinite claims.

### **Claim Rejections - 35 USC § 101**

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 43-54 and 63-82 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility. The instant invention encompasses a method of screening candidate modulator

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compounds of a protein phosphatase 2A (PP2A). The instant application does not disclose a specific biological role for this PP2A phosphatase or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

The instant claims are drawn to a method of screening candidate modulator compounds of a protein phosphatase 2A (PP2A) by testing the activity of PP2A in the presence of a candidate compound wherein a difference in the activity of PP2A identifies the modulator of PP2A. The instant specification discloses that the invention is based on the working hypothesis that “PP2A/By deregulation is associated with development of bipolar disorder” (p. 10 of the specification) and that “modulation of the phosphorylation state of KCNQ [a putative ion channel] channels, which represents a balance between the activities of kinases and phosphatases, is believed to be important for control of neuronal excitability” (middle at p. 3). Example 6 at p. 36 demonstrates interaction between KCNQ polypeptides and PP2A/By *in vitro*, and Example 15 at pp. 47-53 presents analysis of genetic variations within KCNQ2 gene of patients affected by bipolar disorder.

The instant specification asserts significance of interaction between PP2A/By and KCNQ polypeptides and bipolar disorder or mental disorders in general. However, the evidence of record fails to support this assertion. The instant specification fails to present any evidence or sound scientific reasoning that PP2A/By and KCNQ interaction has any significance with respect to any pathological condition, including mental disorders. According to the instant specification, “PP2A/By modulator” is “a compound that increases or decreases the activity of a PP2A/By polypeptide and/or a compound that increases or decreases the transcription level of the

PP2A/B $\gamma$  mRNA encoding said polypeptide”, p. 16. Thus, based on the definition of “a modulator”, it is reasonable to allege that because any compound would either increase or decrease the activity of PP2A/B $\gamma$ , then any compound would meet the limitation of a “modulator” of activity of PP2A/B $\gamma$ . In the absence of knowledge of the biological significance of the activity of this specific PP2A/B $\gamma$  or the interaction between PP2A/B $\gamma$  and KCNQ, there is no immediately obvious patentable use for the claimed method of measuring the activity of PP2A/B $\gamma$ . To employ the modulator identified by the claimed method in the future methods of treating mental disorders is not a “real world” because it would eventually relate to PP2A/B $\gamma$  and KCNQ proteins for which no biological function is known. Because the instant specification does not teach a biological significance of PP2A/B $\gamma$  and/or KCNQ, which supports a practical utility of the claimed invention, one would not reasonably believe that the administration of a modulator identified by the claimed method would prevent or treat a condition or disease, like bipolar disorder, schizophrenia and depression, as implied by the specification.

The instant specification discloses PP2A phosphatase and KCNQ polypeptides and asserts their association with mental disorders. However, Applicant’s assertion lacks support in the specification or in the evidence of record. There is little doubt that, after complete characterization, this PP2A phosphatase and/or KCNQ may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant’s claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which the court expressed the opinion that all chemical compounds are

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“useful” as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed “real world” utility. The court held that:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility”, “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion”.

To practice the instant claimed method of screening candidate modulators of PP2A phosphatase would clearly be using the claimed invention as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible “real world” use for the method of screening for modulators of PP2A, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

### ***Claim Rejections - 35 USC § 112***

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 43-54 and 63-82 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Double Patenting***

14. Claims 43-45 of this application conflict with claims 113-115 of Application No. 10/744,796. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

15. Claims 43-45 are and 63-82 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 113-115 of copending Application No. 10/744,796. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

***Conclusion***

16. No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

April 17, 2007